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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,755

03/29/2006

Hiroshi Fukushima

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EXAMINER

MARCETICH, ADAM M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,755	Applicant(s) FUKUSHIMA ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06 July 2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Japan 2003-340851, filed on 30 September 2003 has been received. A priority date of 30 September 2003 is given to claims 1-9.

Claim Objections Claim 3 is objected to because of the following informalities: the language "the opposed films" appearing on lines 3-4 lack proper antecedent basis. While the preceding claims 1 and 2 recite the language "container outer members" and "synthetic resin film," the claim language describing this structure should be amended for proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claim 8 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The step of "visually recognizing" has no transformative effect on an object, since it is only being observed.

5. Claim 8 provides for the use of a partition wall, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2173.05(q).

Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

In other words, a step of "visually recogniz[ing]" a container condition without any manipulation steps is interpreted as a mental process, and therefore not a category of invention. Examiner suggests amending the claim to recite a step of separation of the partition wall that is "capable of being visually checked" or similar language to remove a mental process from the claim scope, and further explaining the step of "separat[ing]."

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 8 provides for the use of a partition wall, but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2173.05(q).

35 USC § 112, 6th Paragraph

9. With regard to Applicant's "separation display means" of claims 1, 4-7 and 9, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

- (A) The claim limitations must use the phrase "means for" or "step for;"
- (B) the "means for" or "step for" must be modified by functional language;
and
- (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

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If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

In the instant case, Examiner considers the peel seal area 25 as taught by Hustad to be an equivalent to the "separation display means" claimed by Applicant, since it performs the same function (allowing visual checking prior to separation and no longer being visually recognized after separation) in the same way (separation display means cannot be seen after separation, immediate specification ¶ [0024]), with the same result (obscuring an indication) as the device disclosed by Applicant. Additionally, the peel seal area 25 as taught by Hustad is the structural equivalent of the claimed separation display means, since it comprises a film layer printed with indicia. See MPEP 2183.

10. Regarding claims 1, 5, 6, and 9, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification.

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11. Regarding claims 4 and 7, Applicant appears to not meet the requirements set forth in MPEP §2181, since the claims contain sufficient structure for producing the claimed "separation display means."

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1-4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inuzuka et al. (US Patent Application Publication No. 2001/0000042) in view of Hustad et al. (US Patent 5,064,664).

15. Regarding claim 1, Inuzuka discloses a medical container having a separable partition wall which is formed by heat-welding or bonding parts of container outer members of the medical container opposed to each other (¶ [0041], [0042], Fig. 1, infusion solution bag 1A having weak seal portion 5 formed by heat sealing process).

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Inuzuka discloses the invention substantially as claimed. However, Inuzuka lacks separation display means as claimed [claim 1]. Hustad discloses a package for hermetically sealing consumable products (col. 1, lines 8-15, col. 4, lines 9-28, especially lines 16-22) further comprising:

separation display means capable of displaying an operation for separating the partition wall is provided on a partition wall section of at least one of the container outer members of the medical container (col. 4, lines 9-28, especially lines 16-22, col. 5, lines 40-55, Figs. 5-6, peel seal area 25); and

the separation display means can be visually checked from outside the container outer member opposed to the container outer member on which the separation display means is provided prior to separation of the partition wall (col. 6, lines 25-33, Figs. 10-11, transparent front panel 41 and opaque rear panel 42). To clarify, an opaque rear panel allows viewing only from a side opposed to the container outer member on which separation display means is provided. Hustad provides the advantage of indicating upon even casual examination when a package has been opened due to either tampering or normal use (col. 4, lines 9-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Inuzuka as discussed with the separation display means as taught by Hustad in order to allow quick examination of package.

16. Regarding claim 2, Inuzuka discloses a medical container comprising container outer members made of synthetic resin film (§ [0040], Fig. 1, transparent flexible plastic films 2a, 2b).

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17. Regarding claim 3, Inuzuka discloses a medical container comprising a multiple-chamber container (§ [0040], Fig. 1, infusion solution bag 1A);

which has a separable partition wall formed by heat-welding parts of the container outer members (§ [0042], weak seal portion 5 formed by heat sealing process); and

has a plurality of chambers partitioned by the partition wall (§ [0041], Fig. 1, chambers / sections 7a, 7b).

18. Regarding claim 4, Inuzuka discloses the invention substantially as claimed, see above. However, Inuzuka lacks separation display means as claimed [claim 4]. Hustad discloses:

separation display means having a symbol display section (col. 6, lines 25-33, Figs. 10-11, message information 45); and

a symbol covering section provided outside the symbol display section (col. 6, lines 25-33, Figs. 10-11, rear panel 42); and

the symbol covering section covers the symbol display section such that the symbol display section cannot be visually recognized from outside the container outer member on which the separation display means is provided (col. 6, lines 25-33, Figs. 10-11, rear panel 42 disclosed as opaque and therefore preventing the symbol display section from being visually recognized from outside the container outer member on which the separation display means is provided). Hustad provides the advantage of allowing even minor openings of a peel seal to be detected (col. 6, lines 18-24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to modify the invention of Inuzuka as discussed with the separation display means as taught by Hustad in order to detect even minor openings of a peel seal.

19. Regarding claim 8, Inuzuka discloses a method of using a medical container which includes a separable partition wall formed by heat-welding or bonding parts of opposed container outer members of the medical container (§ [0041], [0042], Fig. 1, infusion solution bag 1A having weak seal portion 5 formed by heat sealing process). Inuzuka discloses the invention substantially as claimed, see above. However, Inuzuka lacks separation display means as claimed [claim 8]. Hustad discloses:

separation display means capable of displaying an operation for separating the partition wall provided on a partition wall section of at least one of the container outer members of the medical container (col. 4, lines 9-28, especially lines 16-22, col. 5, lines 40-55, Figs. 5-6, peel seal area 25);

the separation display means being visually checked from outside the container outer member opposed to the container outer member on which the separation display means is provided prior to separation of the partition wall (col. 6, lines 25-33, Figs. 10-11, transparent front panel 41 and opaque rear panel 42);

the method being characterized in that:

the partition wall section on the opposed container outer members is divided by separating the partition wall provided on the medical container (col. 5, lines 49-56, message information 31 obscured when package is opened);

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in the condition where the separation display means can be seen from outside the container outer member opposed to the container outer member on which the separation display means is provided (col. 6, lines 25-33, Figs. 10-11, transparent front panel 41 and opaque rear panel 42); and

separation of the partition wall is visually recognized based on the condition where the separation display means cannot be seen (col. 5, lines 49-56, message information 31 obscured when package is opened. Also see col. 5, lines 30-36, phrases such as "safety seal" which are obscured upon seal disruption.). Hustad provides the advantage of allowing quick examination of package as discussed for claim 1 above.

20. Regarding claim 9, Inuzuka discloses a method of using a medical container which includes:

a separable partition wall formed by heat-welding or bonding parts of opposed films of the medical container (§ [0041], [0042], Fig. 1, infusion solution bag 1A having weak seal portion 5 formed by heat sealing process); and

a plurality of chambers partitioned by the partition wall (§ [0041], Fig. 1, chambers / sections 7a, 7b). Inuzuka further discloses a step where the plural chambers are brought into a state where the chambers can communicate with each other so that a plurality of contents accommodated in the respective chambers inside the container can be mixed or dissolved (§ [0047], pressure applied to weak seal portion 5 and mixing solution). Inuzuka discloses the invention substantially as claimed, see above. However, Inuzuka lacks separation display means as claimed [claim 9]. Hustad discloses:

separation display means capable of displaying an operation for separating the partition wall provided on a partition wall section of at least one of the films of the medical container (col. 6, lines 25-33, Figs. 10-11, message information 45);

the separation display means being visually checked from outside the film opposed to the film on which the separation display means is provided prior to separation of the partition wall (col. 6, lines 25-33, Figs. 10-11, rear panel 42 disclosed as opaque);

the method being characterized in that:

the partition wall section on the opposed films is divided by separating the partition wall provided on the medical container in the condition where the separation display means can be seen from outside the film opposed to the film on which the separation display means is provided (col. 6, lines 25-33, Figs. 10-11, opaque rear panel 42 and transparent front panel 41);

separation of the partition wall is visually recognized based on the condition where the separation display means cannot be seen (col. 5, lines 49-56, message information 31 obscured when package is opened. Also see col. 5, lines 30-36, phrases such as "safety seal" which are obscured upon seal disruption.). Hustad provides the advantage of allowing quick examination of package as discussed for claim 1 above.

Regarding the limitation of "separation display means [that] cannot be seen by the interruption of the contents," Examiner notes that the claim is drawn to a medical container and method of using, not the specific contents of the bag. To clarify, the structure of the container and steps in its method of using are considered when

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evaluating for patentability. Since the invention of Inuzuka in view of Hustad is capable of obscuring a separation display means as claimed [claim 9], the claim is considered obvious over Inuzuka in view of Hustad.

21. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inuzuka et al. (US Patent Application Publication No. 2001/0000042) in view of Hustad et al. (US Patent 5,064,664), further in view of Brochman (US Patent 3,923,198).

22. Regarding claims 5-7, Inuzuka in view of Hustad discloses the invention substantially as claimed, see above. However, Inuzuka in view of Hustad lacks separation display means as claimed [claims 5-7]. Inuzuka in view of Hustad discloses only a separation display means printed directly on a separation display means (Hustad, col. 5, lines 7-20, peel seal area 25 and peel seal message indicia 27 formed by heat seal bar). In other words, Inuzuka in view of Hustad is silent regarding separation display means provided or printed on an outer surface as claimed [claims 5 and 6], and lacks a film as claimed [claim 7].

Brochman discloses a tape closure system having an opacifying layer and obscuring effect (col. 1, lines 44-46, 53-62, col. 3, lines 37-43), further comprising separation display means provided on an outer surface of a container (col. 4, lines 10-19, Fig. 1, indicator strip 16). Indicator strip 16 as taught by Brochman is provided and printed on an outer surface of a container, and printed on a film attached to an outer surface of a container outer member (Fig. 1, indicator strip 16 provided outside of can lid 10). Brochman provides the advantage of simultaneously hermetically sealing an

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aperture and providing tamper indication (col. 4, lines 10-19, film 26 and adhesive 28 sealing aperture 12). This is valuable in the present invention since a bag containing separate medical products often require sealing an edge during manufacture.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Inuzuka in view of Hustad as discussed with the separation display means as taught by Brochman in order to simultaneously seal an opening and provide tamper indication.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ❖ Schaefer; Richard M. et al. US 4557505
- ❖ Ezaki T. et al. US 6682517
- ❖ Smith; Christopher A. US 5798169
- ❖ Jones, Jr.; Ernest Charles US 3854581
- ❖ Van Erden; Donald L. et al. US 4786190

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
8 September 2008